					ATTY DOCKET NO.	Α	PPLICATION N	О.	
6	PE				022438.43867		09/9	65,738	
/	INFO	ORMATION DISCLOSURE	CITATION		APPLICANT(S)				
/		(Bs) several sheets if necess	ary)		O'Brien, et al. FILING DATE		ROUP ART UN	IIT .	
DEC	01	الق المالية			September 27, 20	1	1647	>	
*EXAMINER			u.s	PATENT	DOCUMENTS	01		-	
- TO 1	MADE	EMARIE	T). PAICITI	DOCUMENTS		, ,		
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE		NAME	CLASS	SUBCLASS	FILING DATE IF APPROPE	
				-	* · · · · · · · · · · · · · · · · · · ·				
	L		U.S. PATEN	IT APPLIC	ATION PUBLICATIONS				
*EXAMINER		DOCUMENT NUMBER	DATE		NAME	CLASS	SUBCLASS	FILING DATI	

					and the second				
									
		,1,	FORE	IGN PATE	NT DOCUMENTS				
		DOCUMENT NUMBER	DATE		COUNTRY	CLASS	SUBCLASS	TRANS!	LATION NO
(%)	AA	WO 00/36107	06/22/00	World		C12N 15/12	C07K 14/47	√ √	110
	вв	0 288 082	10/26/88	Europe		C07K 15/14	C12P 21/00	1	
	сс	WO 02/092836	11/21/02	World		C12Q		1	
		OTHER DOCUME			, Title, Date, Pertinent P				
\mathcal{S}		DD T.J. O'Brien, et al. The International Journ	al of Biological M	Markers, V	out the antigen, its structure ol. 13, no. 4, pp. 188-195				
W		"Isolation and Characte Identification as a Mucin Kenneth O. Lloyd, et al. Int. J. Cancer: 71, 842-8	rization of Ovaria 1-type Molecule" 50 (1997)	an Cancer	Antigen CA125 Using a No	w Monoclon	al Antibody (V	/K-8):	
EXAMINE	R C	fangonikel			DATE CONSIDERED 2	7/06			
*EXAMINE considered	R: Initi	tial if reference considered, whether ude copy of this form with next cor	er or not citation is nmunication to ap	in conform	nance with MPEP 609; Draw li	ine through ci	ation if not in or	onformance	and not

Form PTO-A820 (also form PTO-1449)

<u> </u>			Docket Number (Optional)	Application Number
OIPE	ODM	ATION DISCLOSURE CITATION	022438.43867 Applicant(s)	09/965,738
	-3/ ((Use several sheets if necessary)	O'Brien, et al.	
DEC 0 5 50	or E		Filing Date September 27, 2001	Group Art Unit 1642
EXAMINER AND ALEM	\$	OTHER DOCUMENTS (Including Author, Titl	e, Date, Pertinent Pages, Etc.)	
MADEN		"Immunohistochemical Characterization of 22 Mon	oclonal Antibodies against the CA125	5 Antigen 2nd Report from the
$\mathcal{C}_{\mathcal{W}}$	FF	ISOBM TD-1 Workshop" M. Nap, et al. Tumor Bi	ol. 1996: 17: 325-331	
	GG	"Human Mucin Gene MUC5B, the 10.7-kb Large C Super-repeat" Jean-Luc Desseyn, et al. The Journal of Biological Chemistry, Vol. 272, No. 0		_
	нн	"Isolation of the Murine Nbr1 Gene Adjacent to the Julie Chambers, et al. Genomics 38, 305-313 (1996)	e Murine Brcal Gene"	
	n	http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db= "Nucleotide" Lee Helman, M.D., et al. NCBI Sequence Viewer	=nucleotide&val=2566012	
	JJ	"Molecular Cloning of the CA125 Ovarian Cancer Beatrice W.T. Yin, et al. The Journal of Biological Chemistry, Vol. 276, No. 2	· ·	(2001)
	KK	"The CA125 Gene: An Extracellular Superstructur Timothy J. O'Brien, et al. Tumor Biol. 2001; 22: 348-366	re Dominated by Repeat Sequences"	
	LL	"The CA125 Gene: A Newly Discovered Extension Extracellular Superstructure" Timothy J. O'Brien, et al. Tumor Biol 2002; 23: 154-169	of the Glycosylated N-Terminal Doma	ain Doubles the Size of This
			•	
	_	yronilar	DATE CONSIDERED 2/7/06	
*EXAMINER: I not considered.	nitial if c Include o	itation considered, whether or not citation is in conformate copy of this form with next communication to applicant.	nce with MPEP Section 609; Draw line the	rough citation if not in conformance and

P09B/REV04

	011	PE			Docket Number (Optional) 022438.438		application Number 09/9	r _. /965,738	
		RMATEON DISCLOSURE			Applicant(s) O'Brien, et al.	307		,,,,,,,	
DR 1	FEB 0	(Use veral sheets if necessary 2004 u	(ry)		Filing Date		Group Art Unit		
<u> </u>		2 2004			September 27	/, 2001			
	VRAD	DOCUMENT NUMBER		U.S. PAT	TENT DOCUMENTS				
*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE		NAME	CLASS	SUBCLASS	FILING IF APPRO	
3	сс	10/715,066	11/17/03	O'Brien	a, et al.			11/17/03	j
W	DD	10/475,117	10/16/03	O'Brien	n, et al.			10/16/03	j
	<u> </u>		<u> </u>						
			<u> </u>				<u></u>		
	<u> </u>							<u> </u>	
	<u> </u>			<u> </u>			<u> </u>		
							<u> </u>		
	<u> </u>								
	_ 			FOREIG	ON PATENT DOCUMENT	is			
	REF	DOCUMENT NUMBER	DATE	·	COUNTRY	CLASS	SUBCLASS	Trans	slation
			†					120	NO
			 	+			 		
			1				 	 	
				-				 	
	-	 	+				-	-	
	<u></u>		1	OTHER	DOCUMENTS (Includi	ling Author, Title, D	Portinent F	Pages Etc.)	L
	$\overline{}$				DOCONIE. 12 (III.III.	ng Author, 1, 2	ate, 1 eriono	ges, 2,	
	+								
EXAMINE	R G	Forperlihel			DATE CONSIDERED	2/7/06			
EXAMINE not conside	R: Initia	ial if citation considered, whether considered and the considered is the considered and the constant of the co	or not citation is in	n conforman	1ce with MPEP Section 60!		gh citation if no	t in conform:	ance and

			Docket Number (Optional)	Application Number
OIP.	E ORM	ATION DISCLOSURE CITATION	022438.43867 Applicant(s)	09/965,738
'		(Use several sheets if necessary)	O'Brien, et al.	
FEB 0 2	2004		Filing Date September 27, 2001	Group Art Unit 4Z
EXAMINER	ALS!	OTHER DOCUMENTS (Including Author, Titl	e, Date, Pertinent Pages, Etc.)	
CONTIAL P	MARKET	O'Brien, et al.		Duplicate
	AA	"The CA123 Gene: An Extracellular Superstructur Tumor Biology, Vol. 22, 2001 pp. 348-366	e Dominated by Repeat Sequences"	Dopinace
CW	ВВ	Argueso, et al. "MUC16 Mucin is Expressed by the Human Ocular Invest Ophthalmol Vis Sci 2003 Jun:44(6):2487-95	r Surface Epithelia and Carries the H	85 Carbohydrate Epitope"
······································			· · · · · · · · · · · · · · · · · · ·	
	ļ			
		·		
		-		
				<u>.</u>
:				
		· · · ·		
DV 4 5 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4			1	MATERIAL CONTRACTOR CO
EXAMINER	GTA	ug & Nilor	DATE CONSIDERED 2 7	,
*EXAMINER:		itation considered, whether or not citation is in conforman	ce with MPEP Section 600: Draw line the	nugh sitution if not in sonfa
not considered.	Include c	opy of this form with next communication to applicant.	Section 00/, Diam intellife	

P098/REV04

				<u>-</u>	Docket Number (Optional) 022438.4386		Application Number	, 965,738	
K	1/4g	RMATION DISCLOSURE (Use several sheets if necessar	CITATION		Applicant(s) Timothy J. O'Brien	<u>, </u>	03/3	703,730	
- (. 4	1 2015 1 Necessar	y /	Filing Date Group Art Unit					
	WOI,				9/27/01		1	1642	
\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	ion.	TANGUTH.	U.S	. PATENT	DOCUMENTS				
•EXAMINER INITIAL	REP	DOCUMENT NUMBER	DATE		NAME	CLASS	SUBCLASS	FILING IF APPRO	1
Ch	AA	6,335,194	1-1-2002	Bennett	et al.	435/375		2-2-2000)
W	ВВ	6,451,602	9-17-2002	Popoff e	et al.	435/375		3-2-2000)
			U.S. PATENT	T APPLICA	TION PUBLICATIONS				
*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE		NAME	CLASS	SUBCLASS	FILING IF APPRO	
•									
							•		
			FORE	IGN PATE!	NT DOCUMENTS				
	REF	DOCUMENT NUMBER	DATE		COUNTRY	CLASS	SUBCLASS	Trans YES	lation NO
				· · -					
_									
			OTHER D	OCUMEN'	TS (Including Author	, Title, Date, F	Pertinent Pages, Et	[c.)	
									
	\dashv		·						
EXAMINE	R y	ongrenikal	· ·		DATE CONSIDERED	~			
						-06			
EXAMINE! not consider	K: IniVi red. In	al if citation considered, whether o clude copy of this form with next c	r not citation is in ommunication to a	conforman pplicant	ce with MPEP Section 609; I	raw line thro	ugh citation if not	in conforma	ance and

)	e i
1	4
E	
•	

PTO/SB/OSA (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

TECH CENTER 1600/2900	MAR 1 9 2002	
8		

Substitute for form 1449APTO	Complete if Known				
agginino na mani 1445/4 10	Application Number	09/965,738			
INFORMATION DICCLOCURE	Filing Date	September 27, 2001			
INFORMATION DISCLOSURE	First Named Inventor	O'Brien, Timothy J.			
STATEMENT BY APPLICANT	Group Art Unit	Unassigned			
100	Examiner Name	Unassigned			
(use as many medisas (aceseary)	Attorney Docket Number	40715-260477			
Sheet 1 of 3	Express Mail Certificate	EV 032 104 775 US			
MAR 1 1 2002 &		·			

	E		TENT DOCUMENTS		
Cite No.	U.S. Petego ADEMA Number	Kind Code ² (if known)	Name of Patentee or Applicant	Date of Publication Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
 	 			,mm-50-7771	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
	-	- 			
+	 				
	 				
 					
 					
+	+				
—					
┦					
	1	U.S. Pateon	U.S. Petero Becument	U.S. Peterphatument Kind Code ²	U.S. Pateon becument Cite No.* Number (if known) Name of Patentee or Applicant Cited Document

				FOREIG	N PATENT DOCUM	NTS		
		For	eign Patent Do	cument				
Examiner Initials*	Cite No.	Office ³	Number ^a	Kind Code ² (if known)	Name of Patentee or Applicant of Cited Documen	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevent Passages or Relevent Figures Appear	יד
								
								1
	1	1						T
		1						T
	+	1						T^{-}
	—	1						T
		+					· · · · · · · · · · · · · · · · · · ·	T
		1 1				1		T

Examiner	Date	
Signature	Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformation and not considered include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any commitme you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the seriel number of the patent document. ⁸ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁹ Applicant is to place a check mark here if English language Translation is attached.

Complete if Known

09/965,738

Substitute for form 1449APTO

Sheet

2 of

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Filing Date September 27, 200 O'Brien, Timothy J First Named Inventor Group Art Unit Unassigned **Examiner Name** Unassigned 40715-260477 Attorney Docket Number

Application Number

MAR 1 1 2002

Sneet	2 01		19
		TAADEMAR	
		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
xaminer nitials*	Cite No.¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	7
60	1	BAST RC et al., A radioimmunoassy using a monoclonal antibody to monitor the course of epithelial ovarian cancer, N Engl J Med. 309:883-887 (1983)	7
6n	2	BON GC et al., Serum tumer marker immunoassays in gynecologic oncology: Establishment of reference values, Am J Obstet. Gynecol. 174:107-114 (1996)	1
ω	3	CLEMONS-MILLER, A et al. Intrathecal Cytotoxic T-Cell Immunotherapy for Metastatic Leptomeningeal Melanoma. Clinical Cancer Research 7:917s-924s, March 2001 (Suppl.)	,
Duplia	104	DESSEYN JL et al., Human mucin gene MUC5B, the 10.7-kb large central exon encodes various alternate subdomains resulting in a super-repeat. Structural evidence for a 11p15.5 gene family, J Biol. Chem. 272(6):3168-3178 (1997)	,
ÇŅ	5	FENDRICK, JL et al. Characterization of CA 125 Synthesized by the Human Epithelial Amnion WISH Cell Line. <i>Tumor Biol</i> 1993; 14:310-318	Ī
	6	FENDRICK, JL et al. CA125 Phosphorylation Is Associated with Its Secretion from the WISH Human Amnion Cell Line. <i>Tumor Biol</i> 1997; 18:278-289	Ī
	7	FOON, KA et al., Are solid tumor anti-idotype vaccines ready for prime time?, Clinical Cancer Research 7:1112-1115 (2001)	T
	8	GENDLER SJ et al., Epithelial mucin genes, Annu. Rev. Physiol. 57:607-634 (1995)	Ī
	9	GUM Jr., JR, Mucin genes and the proteins they encode: Structure, diversity and regulation, Am J Respir. Cell Mol. Biol. 7:557-564 (1992)	T
	10	GUM JR, Human Mucin Glycoproteins: Varied Structures Predict Diverse Properties and Specific Functions. Biochemical Society Transactions. 23(4):795-799, 1995.	
	11	HARDARDOTTIR H et al., Distribution of CA125 in embryonic tissue and adult derivatives of the fetal periderm, Am J Obstet. Gynecol. 163;6(1):1925-1931 (1990)	
	12	KONISH I et al., Epidermal growth factor enhances secretion of the ovarian tumor- associated cancer antigen CA125 from the human amnion WISH cell line, J Soc. Gynecol. Invest. 1:89-96 (1994)	
	13	LLOYD KO et al., Synthesis and secretion of the ovarian cancer antigen CA125 by the human cancer cell line NIH: OVCAR-3, <i>Tumor Biology</i> 22, 77-82 (2001)	T
	14	LLOYD KO et al., Isolation and characterization of ovarian cancer antigen CA125, using a new monoclonal antibody (VK-8). Identification as a ucin-type molecule, Int. J. Cancer, 71:842-850 (1997)	
W	15	MARSHALL E, DNA Sequencing: Genome teams adjust to shotgum marriage, Science 292:1982-1983 (2001)	Ţ
	16	NAP M et al., Immunohistochemical characterization of 22 monoclonal antibodies against the CA125 antigen: 2 nd report from the ISOBM TD-1 workshop, Tumor Biology 17:325-331 (1996)	- -
W	17	NUSTAD K et al., CA125 – epitopes and molecular size, Int. J of Biolog. Markers, 13(4)196-199 (1998)	,

PTO/	SB/O	ВА	(08-00)
10/31/2002.	OMB	065	1-0031

Please type a plus sign (+) inside this box Under the Paperwork Reduction Act of 1995, no person Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE s are required to respond to a collection of information unless it contains a valid OMB control number

MAR 1 1 2002 Substitute for form 1449APTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Complete if Known **Application Number** 09/965,738 Filing Date September 27, 2001 First Named Inventor O'Brien, Timothy J. Group Art Unit Unassigned Unassigned **Examiner Name Attorney Docket Number** 40715-260477

(use as many sheets as necessary) 3 of Sheet

		18	NUSTAD K et al., Specificity and affinity of 26 monoclonal antibodies against the	1 -
	Ŵ		CA125 antigen: First report from the ISOBM TD-1 workshop <i>Tumor Biology</i>	1
U	YV.	1	17:196-219 (1996)	
	1	19	O'BRIEN, TJ et al. CA 125 Antigen in Human Amniotic Fluid and Fetal	+
	l		Membranes. Am J Obstet Gynecol 155:50-55 July, 1986	/
		20	O'BRIEN, TJ et al. New Monoclonal Antibodies Identify the Glycoprotein	
	ł		Carrying the CA 125 Epitope. Am J Obstet Gynecol 1991; 165-1857-64	/
		21	O'BRIEN, TJ et al. More Than 15 Years of CA 125: What Is Known about the	 _
/			Antigen, Its Structure and Its Function. The International Journal of Biological	/
			Markers 13:188-195 (1998) —DUPLICE TO THE INTERNATIONAL JOURNAL OF BIOLOGICAL	
		22	QUIRK, JR et al. CA 125 in Tissues and Amniotic Fluid During Pregnancy. Am J	
6	J		Obstet Gynecol 159:655-649 (1988)	/
1		23	SANTIN, AD et al. Induction of Ovarian Tumor-Specific CD8+ Cytotoxic T	
ĺ			Lymphocytes by Acid-Eluted Peptitde-Pulsed Autologous Dendritic Cells.	1
i			Obstetrics & Gynecology 2000; 96:422-30	l
		24	SANTIN, AD et al. In vitro Induction of Tumor-Specific Human Lymphocyte	
		1	Antigen Class I-Restricted CD8+ Cytotoxic T Lymphocytes by Ovarian Tumor	'
j			Antigen-Pulsed Autologous Dendritic Cells from Patients with Advanced Ovarian	
- 1			Cancer. Am J Obstet Gynecol 2000; 183:601-9	
		25	SHIGESMASA, K, et al. p21: a Monitor of p53 Dysfunction in Ovarian Neoplasia.	1
\			International Journal of Gynecologic Cancer 7:296-303, 1997.	
		26	SHIGESMASA, K, et al. p16 Overexpression: A Potential Early Indicator of	7
			Transormation in Ovarian Carcinoma. J Soc Gynecol Invest 4:95-102, 1997.	'
		27	VERMA M et al., Mucin genes: Structure, expression and regulation,	-
			Glycoconjugate J. 11:172-179 (1994)	
}		27	WAGNER, U. et al. Immunological Responses to the Tumor-Associated Antigen	7
- 1			CA125 in Patients with Advanced Ovarian Cancer Induced by the Murine	ľ
			Monoclonal Anti-Idiotype Vaccine ACA125. HYBRIDOMA 16:33-40 (1997)	
- 1		29	WAGNER U et al., Immunological consolidation of ovarian carcinoma recurrences	1
- (with monoclonal anti-idiotype antibody ACA125: Immune responses and survival	
			in palliative treatment, Clin. Cancer Res. 7:1112-1115 (2001)	
- 1		30	WILLIAMS, SJ et al. MUC13, a Novel Human Cell Surface Mucin Expressed by	7
1			Epithelial and Hemopoietic Cells. The Journal of Biological Chemistry	
			276(21):18327-18336, 2001.	
1		31	YIN TWT et al., Molecular cloning of the CA125 ovarian cancer antigen.	7
			Identification as a new mucin (MUC16), J Biol. Chem. 276:27371-27375 (2001)	
		32	ZURAWSKI VR et al., Tissue distribution and characteristics of the CA125	7
'			antigen, Cancer Rev. 11-12:102-118 (1998)	

Evening		
Examiner	Date	
Signature Manual Symbol		1 212/06
T WIN GO Y II) I VOO JOC 1	Considered	1217106

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformation and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231. 911366

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.